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Oridion

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3.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Product name

Proprietary:
Microstream[1] O_2/CO_2 Oral Nasal Filterline[1]

Common:
Oral Nasal Cannula Gas sampling line for use with a capnograph with integrated Oxygen Administration means for simultaneously administering supplemental oxygen projected near the nose and mouth for inhalation.

Establishment registration number

Establishment registration number: 8044004

Establishment address:

Oridion Medical 1987 Ltd.
Har Hotzvim Science Based Industrial Park
POB 45025
91450 Jerusalem, Israel

Device listing FDA form 2892:

A 733250

Product Classification

The Microstream O_2/CO_2 Oral Nasal Cannula Filterline sample line is classified Class II, Product Code 73 CCK.

Intended use:

The Microstream O_2/CO_2 Oral Nasal Filterline device is used whenever the physician needs to collect a sample of the patient's breathing to measure CO_2 with a capnograph while simultaneously administering supplemental oxygen near the nose and mouth for inhalation. It can be used for adult, intermediate or pediatric non intubated patients. The device is intended to be used with monitors using Oridion Microstream technology.

[1] Microstream and FilterLine are registered trademarks of Oridion Medical 1987 Ltd.

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Device description

The common product name for this device Oral Nasal Cannula Gas sampling line for capnograph with integrated Oxygen Administration means for simultaneously administering supplemental oxygen projected near the nose and mouth for inhalation.

The gas sampling cannula is used with a capnograph (carbon dioxide analyzer 21CFR 868.1400). There is a Sampling Cannula at one end of the device for connecting to the patient's nose and mouth and a Female Luer Lock on the other end for connecting to the Capnograph.

The two connectors are joined by a plastic tube and an in line hydrophobic filter.

One end of the tube is connected to the source of the patient's exhalation (nose and mouth and the other end of the tube is connected to a capnograph. The capnograph has a pump that creates a vacuum of approximately 30mbar which draws a sample of the patient's breathing (exhalation) through the sampling tube into the capnograph.

Substantial equivalence

The device is essentially equivalent to Salter Labs PN 4003 Adult dual oral nasal CO_2 sample cannula with oxygen delivery (K864902), Salter Labs PN 4103 Pediatric dual oral nasal CO_2 sample cannula with oxygen delivery (K864902) and the Microstream O_2/CO_2 Nasal Cannula Filterline (K010024) modified by adding an oral sampling prong.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2001

Mr. Sandy Brown
Oridion Medical 1987 Ltd.
P.O. Box 45025
Jerusalem 91450
Israel

Re: K011536
Microstream® O_2/CO_2 Oral Nasal Filterline®
Regulation Number: 868.1400
Regulation Name: Carbon-Dioxide Gas Analyzer
Regulatory Class: II (two)
Product Code: 73 CCK
Dated: October 31, 2001
Received: November 5, 2001

Dear Mr. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011536

Oridion

T"03 NOV 1 4 2001

T"03

April 2, 2001

5.0 Indications For Use

510(k) Number (if known): K011536

Device Name:

May 2, 2001

Indications For Use:
Device Name:
Microstream O_2/CO_2 Oral Nasal Filterline

Indications For Use:

The Microstream O_2/CO_2 Oral Nasal Filterline device is used whenever the physician needs to collect a sample of the patient's breathing to measure CO_2 with a capnograph while simultaneously administering supplemental oxygen near the nose and mouth for inhalation. It can be used for adult, intermediate or pediatric non intubated patients. The device is intended to be used with monitors using Oridion Microstream technology.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011536